REMARKS

Claims 1-16 and 18-20 are pending. Favorable reconsideration is respectfully requested in light of the following remarks and data attached hereto.

At the outset, Applicants would like to thank Examiner Pulliam for helpful suggestions during the courteous discussions of the present invention and the Office Action in overcoming the rejections in the outstanding therein. Further, Applicants thank Examiner Pulliam for indicating that the data enclosed herewith in the form of an **signed** 132 Declaration would further favorable prosecution. **A signed 132 Declaration is now attached** hereto as indicated in the Amendment and Request for Reconsideration filed November 21, 2003.

The rejection of Claims 1-20 under 35 U.S.C. §103(a) over Yajima et al is discussed below. Applicants thank the Examiner for providing Applicants a copy of Yajima et al.

Yajima et al discloses, at best, a composition for oral preparation, containing a complex formed by an unpleasantly tasting drug and a polymer with a substance having a low-melting point, as well as a sugar alcohol (see Abstract).

In direct contrast to Yajima et al, the claimed invention relates to a pharmaceutical composition comprising a drug having a disagreeable taste, a wax, and a sugar alcohol. Further, the composition has a particle size ranging from 50 to 200 μm and is able to flow through a tube having a diameter of at most 1 mm without clogging the tube. The example at page 22-25 of the present specification demonstrate that such a composition clearly has no clogging problems.

In light of the above, it is clear that Yajima et al. fails to provide motivation to optimize the composition disclosed therein to have a particle size of from 50 to 200 μm and have the ability to flow through a tube having a diameter of at most 1 mm without clogging. Therefore, one reading the cited references, at best, is left with merely picking and choosing from a multitude of characteristics of the disclosed composition without any disclosure, guidance and/or enablement of such characteristics. Therefore, Yajima et al fails to disclose the claimed composition. Further, no *prima facie* case of obviousness can be sustained based upon the English-language Abstract of Yajima et al. Further, is fails to disclose or suggest all claim limitations, Yajima et al can not possibly sustain a *prima facia* case of obviousness.

In light of the above, Yajima et al clearly fails to disclose or suggest all limitations of the claimed invention as required by the MPEP (see § 2143.03 and the enclosed copy of *In re Royka* 180 USPQ 580 (CCPA 1974)). Accordingly, any combination of the above-mentioned references clearly fails to anticipate the claimed invention, much less suggest it. Additionally, it has not been pointed out to the Applicants as to where any specific motivation lies within any of the above-mentioned references that would motivate the skilled artisan reading the same to modify the process disclosed therein towards the claimed invention.

In light of the above, it appears as if the Examiner is relying on the Applicants disclosure to supply motivation to modify the disclosure of Yajima et al to arrive at the claimed invention. However, this is clearly improper according to a recent decision (enclosed) by the U.S. Federal Courts in *In re Lee* (61 USPQ2D 1430 (CA FC 2002)). The *Lee* Court indicated that the Office must provide specific motivation, hint, or suggestion, found in the references relied upon to support a *prima facia* case of obviousness. In the

present case, the Office appears to rely on the present specification for motivation, which is clearly forbidden according to the *Lee* Court. In light of this decision, Applicants respectfully request the Office not to use the present specification as a guidepost to combine the disparate disclosures of the cited references (see the enclosed decision in *In re Vaeck* 20 USPQ 2d 1438).

In light of the above, no *prima facia* case of obviousness can possibly exist over any combination of Yajima et al. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

Even if the Office maintains a *prima facia* case of obviousness over Yajima et al, Applicants enclose herewith an 132 Declaration demonstrating that the claimed products, methods and compositions having a particle size ranging from 50 to 200 μm are superior to that of the closest exemplified embodiment that do not possess a particle size ranging from 50 to 200 μm.

The enclosed test data demonstrate that the particle size ranging from 50-200 :m of the granule is able to bring substantial improvement to the qualities of the claimed composition, i.e., by enhancing favorable sensation and preventing the throat from irritation. Applicants respectfully suggest that the enclosed data demonstrates that the claimed composition having sand particle laze ranging from 50-200 μm is superior to compositions failing to be adjusted to said range.

Meanwhile, it can be deduced from Table 2 of the present specification as originally filed that the claimed granule composition can flow through a tube having a diameter of at most 1 mm without clogging the tube. By this table, the secondary granule proved to be able

to flow through said tube without the clogging. Therefore, the primary granule having a particle size ranging from 50-200 μm can more easily flow through said tube without any clogging. Thus Applicants respectfully suggest that said ability is already evident from the existing data of the present specification.

The data is reproduced below for the Examiner's convenience as Supplemental Examples 1 and 2.

Supplemental Example 1

Glycerin monostearate (230 parts by weight) was melted at 90°C, and polyoxyethylene (20) sorbitan monostearate (polysorbate 80) (3 parts by weight) was added thereto. Ticlopidine hydrochloride (100 parts by weight) was uniformly dispersed in the resultant mixture. The dispersion was spray-cooled by use of a spray drier to thereby obtain minute granules.

Supplemental Example 2

Glycerin monostearate (225 parts by weight) was melted at 95°C, and polyoxyethylene (20) sorbitan monostearate (polysorbate 80) (3 parts by weight) was added thereto. Ticlopidine hydrochloride (100 parts by weight) was uniformly dispersed in the resultant mixture. The dispersion was spray-cooled by use of a spray drier to thereby obtain minute granules.

Test methods

1) Favorable sensation:

Each of the granules was put in the mouth, and favorable sensation was tested while said granule was held in the mouth for a period of 30 seconds. The favorable sensation was evaluated on the following criteria.

A: No perceivable roughness was manifested.

B: Roughness was slightly perceived, but was tolerable.

C: Roughness was perceived.

2) Irritation of the throat:

Each of the granules was punt in the mouth, and the irritation of the throat was tested while said granule was held in the mouth for a period of 30 seconds. The irritation of the throat was evaluated on the following criteria.

A: No perceivable irritation was manifested.

B: Irritation was slightly perceived.

C: Irritation was perceived.

The results are shown in the following tables.

Particle sizes (μm)	Favorable sensation	
	Supplemental Example 1	Supplemental Example 2
> 250	C	C
150-250	C	C
125-150	B	B
110-125	A	A
75-110	A	A
50-75	A	A
<50	A	A

Table 2

Particle sizes (μm)	Irritation of the throat	
	Supplemental Example 1	Supplemental Example 2
> 250	A	A
150-250	A	A
125-150	A	A
110-125	A	A
75-110	A	A
50-75	B	B
<50	B	C

Results

Table 1 shows that favorable sensation is not satisfied when the particle size of the granules exceeds a range of 150-250 μm. Meanwhile, Table 2 shows that the granules could cause irritation to the throat when the particle size is less than 50 μm. Taken together, it is considered that the claimed composition having the particle size ranging from 50 to 200 μm is superior to compositions not falling within such a range.

In light of the data enclosed in the **signed** 132 Declaration which is summarized above that demonstrates superiority of the claimed particle size ranging from 50 to 200 μm, combined with the lack of specificity found in Yajima et al. which fails to mention particle size at all, Applicants respectfully submit that the present invention is neither disclosed, nor suggested by Yajima et al.. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Applicants respectfully submit that the present application is now in condition for allowance. Favorable reconsideration is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact the undersigned by telephone.

Respectfully submitted,

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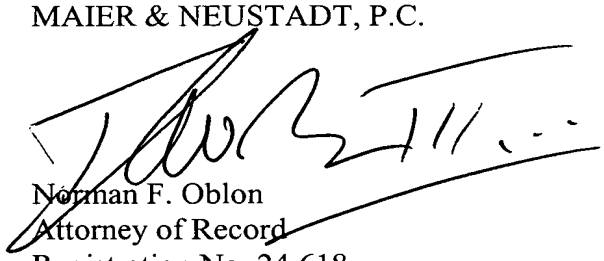
MAIER & NEUSTADT, P.C.



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